DDM

Display Date 8-20-04
Publication Date 8-23-04
Certifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 2003N–0390]

Dental Devices; Dental Noble Metal Alloys and Dental Base Metal Alloys; Designation of Special Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is amending the identification and classification regulations of gold-based alloys and precious metal alloys for clinical use and base alloys devices in order to designate a special control for these devices. FDA is also exempting these devices from premarket notification requirements. The agency is taking this action on its own initiative. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance documents that would serve as special controls for these devices.

DATES: This rule is effective [*insert date 30 days after date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext.123, e-mail: *mea@cdrh.fda.gov.*

ch0422

2003N-0390

NFR 1

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the Medical Devices Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are as follows: Class I (general controls), Class II (special controls), and Class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as preamendments devices. Under the 1976 amendments, class II devices are identified as those devices in which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but for which there is sufficient information to establish a performance standard to provide such assurance.

The SMDA broadened the definition of class II devices to include those devices for which general controls would not provide reasonable assurance of the safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance. The special controls include performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary to provide such assurance. See section 513(a)(1)(B) of the act.

FDAMA added, among other sections, a new section 510(m) to the act (21 U.S.C. 360(m)). Under new section 510(m) of the act, FDA may exempt a class II device from premarket notification requirements (510(k)) (21 U.S.C. 360(k)), if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

In the **Federal Register** of December 1, 2003 (68 FR 67097), FDA issued a proposed rule to amend the classification regulation of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices. FDA identified the draft guidance documents entitled:"Class II Special Controls Guidance Document: Dental Precious Metal Alloys" and "Class II Special Controls Document: Dental Base Metal Alloys" as the proposed special controls capable of providing reasonable assurance of the safety and effectiveness of these devices. FDA invited interested persons to comment on the proposed rule and the draft guidance documents by March 1, 2004. FDA received three comments.

II. Summary of Comments and FDA Response

FDA received one comment from a consumer and one (in duplicate) from a trade association. Both comments were in support of the proposed reclassification with minor modifications suggested. The subject of the consumer comment was that the name of the regulation "gold based alloys and precious metal alloys for clinical use" is unscientific since gold is, by definition, a precious metal.

FDA agrees that the name of the regulation is redundant and, accordingly, has changed the final rule to modify § 872.3060 to read "noble metal," as the term encompasses all precious metals such as gold. The description "for clinical use" has been deleted because it is clear from the identification that

such use is intended. For precision and clarity, we have also modified the identifications in §§ 872.3060 and 872.3710 to more precisely describe these alloys and their component metals.

The subject of the trade association comment was that: (1) The scope of the dental base metal alloys guidance is not clear as to what alloys are subject to the guidance and (2) the recommendation that the labeling for nickel-containing alloys contain a contraindication for hypersensitive individuals is unnecessary because nickel has been demonstrated to be biocompatible.

FDA agrees that more clarity is needed and has modified the scope of the guidance to define the devices not clearly addressed by the guidance. Regarding the second point, while FDA agrees that nickel has been demonstrated to be biocompatible for this intended use, FDA disagrees that the labeling should not contain a contraindication for nickel hypersensitive individuals. The agency believes this warning is needed to minimize the potential for adverse events associated with improper use of this device. Nickel, although biocompatible, is a known sensitizing agent for a small percentage of the population. FDA believes that removing this warning will increase the risk of the device by potentially exposing nickel-hypersensitive individuals who, otherwise, would not be exposed because of the current warning labels.

III. FDA's Conclusion

Based on the findings outlined in the preamble, FDA concludes that special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of these devices. FDA is designating the guidance documents entitled: "Class II Special Controls Guidance Document: Dental Noble Metal Alloys" and "Class II Special Controls

Guidance Document: Dental Base Metal Alloys" as the special controls that the agency believes will reasonably assure the safety and effectiveness for noble metal alloys and base metal alloys, respectively.

Following the effective date of the final rule exempting the device, manufacturers of these devices will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. If manufacturers cannot comply with these recommendations or equivalent measures, they will not be exempt from the requirements of premarket notification and will need to submit a premarket notification and receive clearance for their device prior to marketing.

IV. Electronic Access

Persons with access to the Internet may access the Center for Devices and Radiological Health web site at *http:///www.fda.gov/cdrh*. A search capability for all CDRH documents is available at *http://www.fda.gov/cdrh/guidances.html*. Guidance documents are available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environmental. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866

directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The purpose of this final rule is to designate a special control for these devices. FDA has designated guidance documents as the special controls. Because manufacturers, including small manufacturers, are already substantially in compliance with the recommendations in the guidance documents, and they will not add substantially to the information manufacturers presently submit, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $110,000,000 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not

contain policies that have substantial direct effects on the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the executive order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

List of Subjects in 21 CFR Part 872

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 872.3060 and the section heading are revised to read as follows:

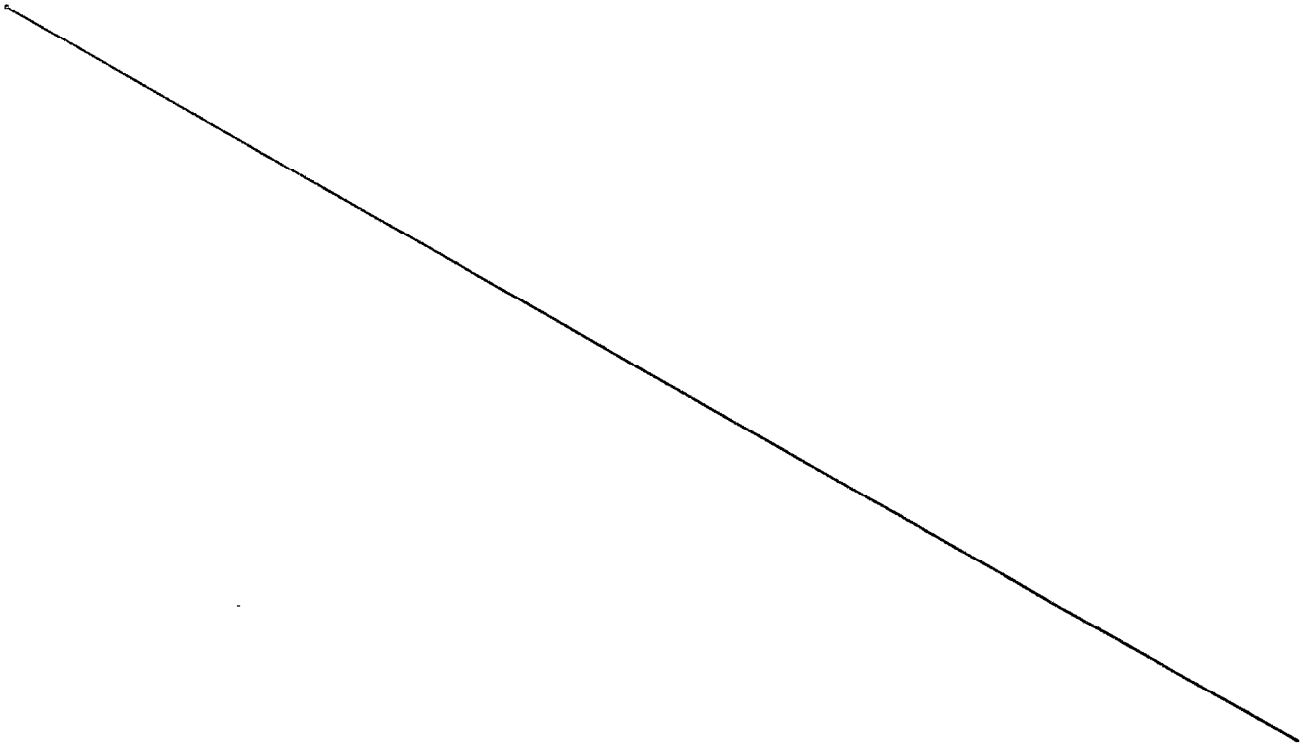
§ 872.3060 Noble metal alloy.

(a) *Identification.* A noble metal alloy is a device composed primarily of noble metals, such as gold, palladium, platinum, or silver, that is intended for use in the fabrication of cast or porcelain-fused-to-metal crown and bridge restorations.

(b) *Classification.* Class II (special controls). The special control for these devices is FDA's "Class II Special Controls Guidance Document: Dental Noble Metal Alloys." The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. See § 872.1(e) for availability of guidance information.

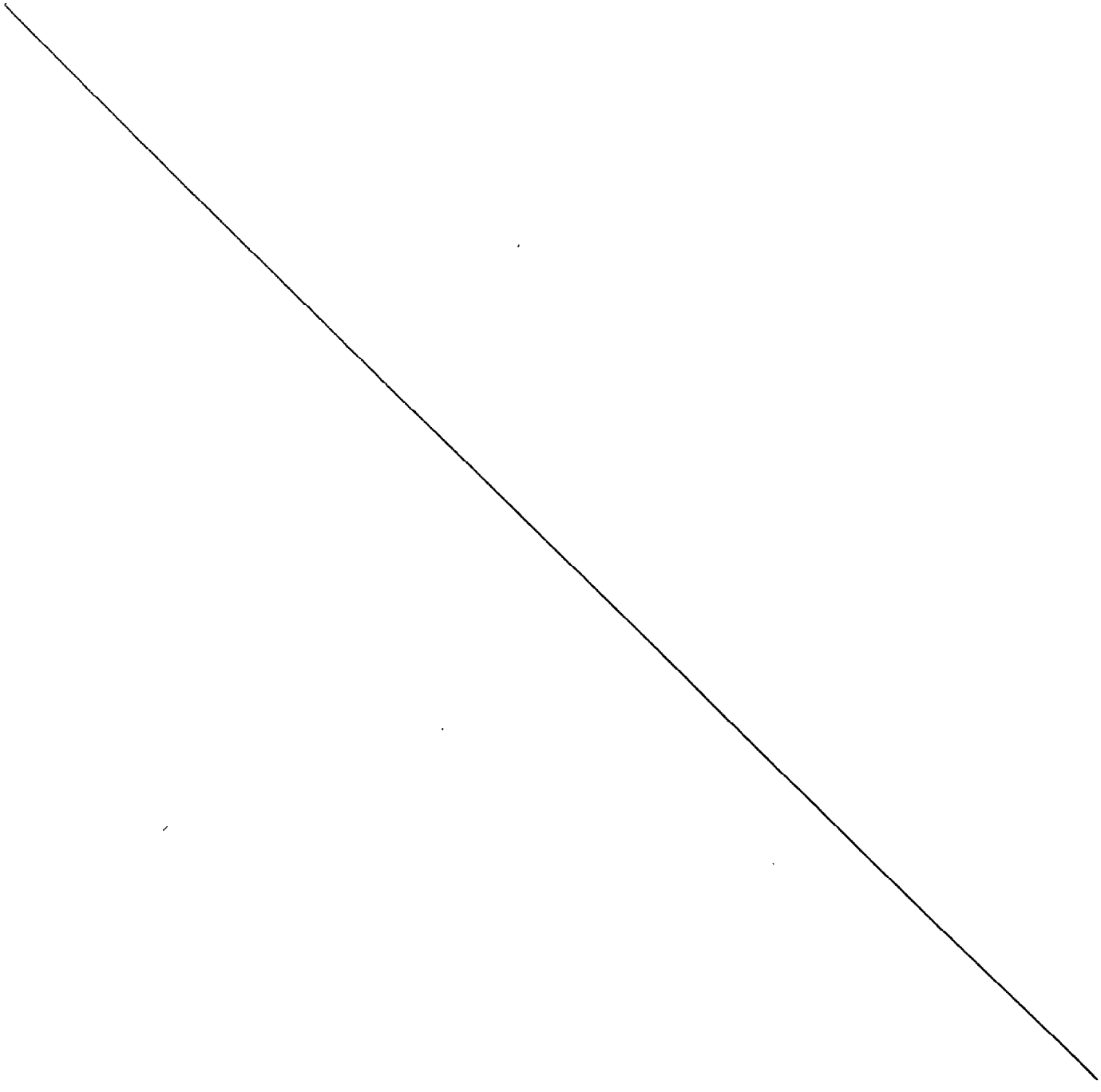
■ 3. Section 872.3710 is revised to read as follows:

§ 872.3710 Base metal alloy.



(a) *Identification.* A base metal alloy is a device composed primarily of base metals, such as nickel, chromium, or cobalt, that is intended for use in fabrication of cast or porcelain-fused-to-metal crown and bridge restorations.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Dental Base



Metal Alloys." The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. See § 872.1(e) for availability of guidance information.

Dated: 8/11/04

August 11, 2004.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S